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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/754,014	NORDSTROM ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,10,14,50-55 and 65-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,10,14,50-55,65-71 and 73-76* is/are rejected.

7)☒ Claim(s) *72* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/1/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

This Office Action is a reply to the Paper filed 28 January 2005 in response to the Non-Final Office Action mailed 31 July 2002. Claims 1-16 and 45-49 were considered in the 31 July Office Action. Claims 1-4, 6-9, 11-13, and 45-49 have been canceled, claims 5, 10 and 14 have been amended and claims 50-76 have been added. Claims 56-64 were subsequently canceled.

Claims 5, 10, 14, 50-55 and 65-76 are presently pending and under consideration.

Response to Amendment

Rejection of claims 1-4, 8, 9, 13 and 45-49 is rendered moot by the cancellation thereof.

Objection to the specification is withdrawn.

New Grounds Necessitated by Amendment

Specification

The amendment filed 28 January 2005, and Sequence Listing and CRF filed 18 August 2004 are objected to under 35 U.S.C. 132 because they introduce new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The paragraph from page 31, line 29 through page 32, line 12 has been amended to set forth sequences CAGGAAAGT, TACTAACGGTTCTTTTTTTCTCTTCACAGG and CAGGTAAAGTGTCTTC, which are identified as fragments of SEQ ID NO: 13. First, the sequence CAGGTAAAGT does not appear in SEQ ID NO: 13. Although, the other sequences

can be found in SEQ ID NO: 13, they are not contemplated in any context other than within the entire sequence set forth as SEQ ID NO: 13. As the sequence fragments set forth in the amendment were not previously contemplated as independent entities, they constitute new matter added to the specification.

Likewise, the sequences added to the paragraph from page 33, line 13 through line 24 and to the sequence listing as SEQ ID NO: 18 and 19 constitute new matter. The original paragraph previously read as follows:

> The sequence of the 3' splice site (3' ss) matches the established consensus sequence, Y_{11}NYAG↓G, where Y=C or T, and N=any base. In 3' splice sites, the polypyrimidine tract (Y_{11}) is the major determinant of splice site strength. For optimal splice site function in OPTIVS8B, the length of the polypyrimidine tract was extended to 16 bases, and its sequence was adjusted to contain 7 consecutive T residues.

Thus, the paragraph sets forth a generic consensus sequence Y_{11}NYAG↓G and then describes the OPTIVS8 intron which comprises the sequence set forth as SEQ ID NO: 13. The specification does not explicitly contemplate a genus comprising the sequence Y_{16}NYAG↓G or comprising the sequence TTCTTTTTTTCTCTTCNYAG↓G and does not contemplate any species within the genus other than OPTIVS8. Therefore, the sequences Y_{16}NYAG↓G and TTCTTTTTTTCTCTTCNYAG↓G find neither explicit nor implicit support in the originally filed application.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claim 51 is objected to because of the following informalities: The claim recites, "the intron comprises a 5' splice having the sequence of SEQ IDNO: 10 residues #1 through #9". This appears to be a typographical error, as the sequence referred to is a "splice site".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 10, 14, 50-55, 65-71 and 73-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The MPEP states, "[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." (MPEP § 2163.06). The MPEP further states, "[w]henever the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not

described in the application" (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

First, amended claims 5, 10 and 14, and claims 50-55 as they depend from claims 5, 10 or 14, are most closely related to previously examined claims 5-7, 10-12 and 14-16. In the previously examined claims the 5' splice site was limited to "having the sequence CAGGTAAGT", the branch point was limited to "having the sequence TACTAAC" and the 3' splice site was limited to "having a sequence TTCTTTTTTTCTCTTCACAGG". The skilled artisan would reasonably interpret the phrase "having a sequence NNNN" as requiring that the entire sequence be present. In contrast, the amended claims recite "having a sequence of NNNN" which the skilled artisan would reasonably interpret as requiring only that the sequence comprise some sequence within the defined sequence. For example, the sequence CA is a sequence of CAGGTAAGT, as is GG, TA, CAG, *etc.* As the originally filed disclosure did not contemplate genera of 5' and 3' splice sites and branch points comprising all possible sequence combinations within the sequences CAGGTAAGT, TACTAAC and TTCTTTTTTTCTCTTCACAGG the claims as amended embrace new matter.

Claims 52 and 53 are directed to the plasmid of claim 10, wherein "either the 3' splice site or the alternative splice site is weakened with respect to the other" and wherein "the 3' splice site or the alternative 3' splice site is weakened with respect to the other by changing three consecutive T's to A's". However, the originally filed specification discloses only plasmid

pIN0772, wherein "the relative strength of the first 3' splice site was weakened by site-directed mutagenesis to change three consecutive T's to A's. Thus, in the sequence shown above for the OPTIVS8 intron, the included sequence 5'-CTTTTTTTC-3' was changed to 5'-CTTTAAATC-3'" (paragraph bridging pages 38-39). As the original disclosure does not suggest an embodiment wherein the strength of the "alternative 3' splice site" is weakened with respect to the first 3' splice site or wherein the sequence modification produces any sequence other than 5'-CTTTAAATC-3', the subject matter embraced by claims 52 and 53 includes subject matter not contemplated in the originally filed specification and claims.

Claim 65 is directed to a synthetic transcription unit comprising a synthetic intron comprising a 5' splice site having a sequence MAGGTRAGT, a branch point having a sequence YNYTRAY and a 3' splice site having a sequence Y_{16}NYAGG. For the reasons set forth herein above, the generic sequence Y_{16}NYAGG is not supported by the specification. Furthermore, although the generic sequences MAGGTRAGT and YNYTRAY are disclosed in the specification at page 32, they are disclosed independently of one another and identified only as consensus sequences. The specification does not teach a genus of synthetic transcription units comprising the combination MAGGTRAGT...YNYTRAY... Y_{16}NYAGG as claimed. Therefore, the combination, viewed as a whole, is not supported by the original disclosure and the claim embraces new matter. Claims 66-71 are also rejected on these grounds. Furthermore, as described above, the sequence TTCTTTTTTTCTCTTCNYAGG, recited in claim 67 constitutes new matter.

Claim 73 also limits the 3' splice site to comprising the generic Y_{16}NYAGG, which, for reasons set forth herein above, constitutes new matter. Furthermore, claims 73-75 are limited to

comprising a synthetic intron from about 90 to 200 nucleotides in length. However, the originally filed specification does not contemplate a synthetic intron having a range of 90 to 200 nucleotides in length. Instead, the specification, in the paragraph bridging pages 33-34, teaches that "most naturally occurring introns are 90-200 nt in length" and that the synthetic intron disclosed in the instant application, which is 118 nts, falls within this range. The specification does not support a synthetic intron limited to a size other than 118 nucleotides.

Finally, claims 70 and 75 limit the branch point to being located within the range of 24 to 38 nucleotides upstream from a site of splicing in the 3' splice site. However, the specification teaches only that, in mammals, "[t]he branch point is typically located 18-38 nts upstream of the 3' splice site" and that the branch point in OPTVS8 is located 24 nts upstream from the 3' splice site. There is no disclosure of a synthetic intron comprising a branch point generically limited to being located within the range of 24-38 nts upstream of a 3' splice site as recited in the instant claims. Therefore, the limitation constitutes new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Mascarenhas (IDS #CS) or Petitclerc (1995) *J. Biotechnol* 40:169-178 in view of any one of Mulvihill et al. (IDS #AC), Carrano et al. (IDS AD) or Ligon et al. (IDS AE).

The art was originally applied to claim 1 as follows:

The claim is drawn to an eukaryotic expression vector comprising two transcription units, each of said transcription units comprising, in order from 5' to 3': a transcriptional control sequence; a 5'-untranslated region comprising a synthetic intron; a coding sequence; and a 3'-untranslated region/poly (A) signal.

Mascarenhas and Petitclerc teach all of the components of the transcription unit described above (see especially Mascarenhas page 914, Figure 1 and Petitclerc page 171, Figure 1). Mascarenhas teaches transcription units composed of control sequences from CMV (cauliflower mosaic virus), 5' UTR, synthetic introns of varying compositions, coding sequences and a 3' UTR. Petitclerc teaches transcription units composed of control sequences from human cytomegalovirus (hCMV), 5' UTR, a synthetic hybrid intron containing an adenovirus splice donor and an immunoglobulin G splice acceptor, a bovine growth hormone coding sequence, and 3' UTR.

Mulvihill teaches co-expression of genes in eukaryotic cells (columns 7-11). They teach the coordinated expression of a gene of interest (see column 6) with a gene encoding a

processing and/or stabilizing protein(s). They too describe transcription units with some of the recited elements or components. They also teach that the transcription units for both the gene of interest and the gene encoding a processing and/or stabilizing protein(s) may be on the same vector and that these genes may be controlled by the same or different promoters. At the top of column 11, they teach that the expression units (transcription units) may be on a single expression vector.

Carrano teaches components or elements necessary for gene expression (see especially column 6). They teach the basic elements (paragraph 1), provide examples of elements that are suitable, such as the control sequences from CMV, and polyadenylation signals. And, Carrano teaches certain embodiments wherein the plasmid may contain more than one expression unit (see especially the top of column 36).

Ligon teaches methods of expressing multiple genes, comprising the biosynthetic pathway for antipathogenic agents, in plants. They teach expression cassettes (transcription units) as well as the desirability to put more than one expression cassette on a transformation vector, such as a plasmid, to reduce the number of plant transformations (see especially column 69).

Mascarenhas or Petitclerc teach all of the elements or components of the transcription unit and demonstrate or describe the functions of the recited elements. They teach enhanced expression using a synthetic intron and have incorporated this element for this purpose in a transcription unit. They further teach the recited order of the elements. They do not teach vectors with more than one transcription unit.

Mulvihill, Carrano, and Ligon each teach plasmids with multiple transcription or expression units or expression cassettes for coordinated expression of multiple coding sequences. These references illustrate that, prior to the filing date of the instant application, making expression vectors with multiple transcription units for the coordinated expression of genes in eukaryotic cells was well known.

One of ordinary skill in the art would have been motivated to use the elements taught by Mascarenhas or Petitclerc in a transcription unit to enhance the expression of a gene of interest. The ordinary artisan would have been further motivated to use transcription units patterned after the teachings of Mascarenhas or Petitclerc in polycistronic expression vectors, exemplified by Mulvihill, Carrano or Ligon, to obtain enhanced expression of coding sequences in a coordinated fashion. The latter three references teach the desirability of creating vectors with multiple transcription units or expression cassettes to obtain coordinated expression of genes. The prior art teaches that configuring plasmids with multiple transcription units or expression cassettes reduces the number of transformations for host cells and coordinates expression of "related" genes. Genes may be related as being part of a biosynthetic pathway, as exemplified by Ligon, or have a relationship as described by Mulvihill, wherein the one cassette or unit encodes for the product of interest, while the other cassettes or units encode for products which stabilize or process or augment the activity or function of the product of interest. The ordinary artisan would have had an expectation of success because of the teachings of the prior art, which demonstrate that synthetic introns increase or enhance expression of coding sequences and the existence of polycistronic plasmids which bring about coordinated expression of multiple sequences in eukaryotic cells.

Although the art was not previously applied to claims 5-7, which limited the splice sites and branch points to comprising specific sequence, the newly amended claims require only that the splice sites or branch point comprise a sequence of the sequences set forth (*i.e.*, any two or more contiguous nucleotides; *Id.*). Although the art does not disclose a specific sequence for the branch point and splice sites, the instant application teaches that mammalian intronic splice sites and branch points comprise conserved sequences (see especially the discussion on page 32 and 33). Therefore, the skilled artisan would expect that the intron of the prior art references would comprise at least two contiguous nucleotides present in one of the sequences set forth in the instant claims. Therefore, the claimed invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mascarenhas or Petitclerc in view of Mulvihill, Carrano or Ligon, as applied to clam 1 above and in further view of Zitvogel (IDS CQ).

The art was originally applied to claims 8 and 9 as follows:

The claims are is drawn to a eukaryotic expression vector comprising an intron having variable splicing, a first coding sequence and comprising: a transcriptional control sequence linked with a first and a second coding sequence; a 5' UT region; an intron 5' to the first coding sequence; an alternative splice site 3' to said first coding sequence and 5' to said second coding sequence; and a 3'-UT region/poly (A) signal.

As described above, Mascarenhas, Petitclerc, Mulvihill, Carrano and Ligon teach all of the limitations of the expression units and a vector comprising two coding sequences. Although

they teach a plasmid comprising an intron, they do not teach an intron capable of alternative splicing. Fischer teaches that prokaryotic cloning vehicles (plasmids) are modified to include sequences which facilitate the expression of genes in eukaryotic cells (see especially column 5). They teach elements such as promoters, alternative splice sites and polyadenylation signals are all necessary for gene expression in eukaryotic cells. This reference illustrates that as of 1989 (the filing date of the parent application for the patent), the elements necessary for gene expression in eukaryotic cells was well known. Thus, the ordinary artisan would have been motivated to construct a polycistronic plasmid that comprises an alternative splice site between two coding regions as a means by which to obtain expression of both coding regions and the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

Although the art was not previously applied to claims 10-12, which limited the splice sites and branch points to comprising specific sequence, the newly amended claims require only that the splice sites or branch point comprise a sequence of the sequences set forth (*i.e.*, any two or more contiguous nucleotides; *Id.*). Although the art does not disclose a specific sequence for the branch point and splice sites, the instant application teaches that mammalian intronic splice sites and branch points comprise conserved sequences (see especially the discussion on page 32 and 33). Therefore, the skilled artisan would expect that the intron of the prior art references would comprise at least two contiguous nucleotides present in the sequences set forth in the instant claims. Therefore, the claimed invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dirks et al. (IDS #CT) in view of Rautmann and Breathnach (1985) *Nature* 315:169-178.

The rejection was previously applied to claim 13 as follows:

The claim is drawn to a eukaryotic expression vector comprising: a transcriptional control sequence transcriptionally linked with a first coding sequence, an IRES sequence, a second coding sequence and a 3'-UT region/poly (A) signal, wherein said IRES sequence is between said first and second coding sequences; and a synthetic intron between said transcriptional control sequence and said first coding sequence.

Dirks teaches a dicistronic plasmid for the expression of genes in eukaryotic cells (see especially Figure 1). Their teachings show a plasmid which has a transcriptional control sequence linked to a first coding sequence followed by an IRES sequence, then a second coding sequence and a 3'-UT region. The plasmid also features an intron comprising splice donor and acceptor sites from SV40 Vp2 between the transcriptional control sequence and the first coding sequence. Dirks does not explicitly teach a synthetic intron. Rautmann teaches expression units comprising synthetic introns (see especially Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Dirks to include the synthetic intron of Rautmann according to the teachings of the instant application. The teachings of Dirks and Rautmann can be easily combined by simply substituting the intron taught by Rautmann for the intron of the expression vector taught by Dirks. Motivation to combine these teachings comes from Rautmann, who teaches a significant enhancement of splicing with the introduction of a globin branchpoint sequence into the intron. Because Dirks does not teach an intron comprising a branchpoint sequence, the skilled artisan would be

motivated to use the synthetic intron taught by Rautmann. One would have a reasonable expectation of success in combining these teachings, as Rautmann demonstrates the effectiveness of his intron in mammalian cells and Dirks describes a mammalian expression system.

Although the art was not previously applied to claims 5-7, which limited the splice sites and branch points to comprising specific sequence, the newly amended claims require only that the splice sites or branch point comprise a sequence of the sequences set forth (*i.e.*, any two or more contiguous nucleotides; *Id.*). Dirks teaches a 5' splice site comprising the sequence "GG" a branch point comprising the sequence "AC" and a 3' splice site comprising the sequence "AG" according to the limitations of the instant claim (see especially Figure 1 and the caption thereto). Therefore, the claimed invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

Claim 72 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.
Examiner
Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER